DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

9 46564

APR 23 2004

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Tony Hung
President and CEO
Sunder Biomedical Tech Co.
10F-1, NO 1-67, Wu-Chuan Road
W. Dist. Taichung 403, Taiwan
Republic of China

Dear Mr. Hung:

During an inspection of Sunder Biomedical Tech Co., located at 10F-1 NO 1-76 Wu-Chuan Road, W. Dist. Taichung 403, Taiwan R.O.C, on November 10-14, 2003, an investigator from the United States Food and Drug Administration (FDA) determined that your establishment manufactures Hemodialysis Blood Tubing Sets and AV Fistula Needle Sets and may market these products in the United States in the future. Hemodialysis Blood Tubing Sets and AV Fistula Needle Sets are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 321(h).

The above-stated inspection revealed that your Hemodialysis Blood Tubing Sets and AV Fistula Needle Sets are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, the manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System (QS) regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to validate with a high degree of assurance a process that cannot be fully verified, as required by 21 CFR 820.75(a). For example, validation for your class [redacted] assembly clean room is inadequate in that there is no written validation protocol that identifies the specific locations for air and surface sampling areas, the action level, and the environmental conditions of the clean room at the time the samples were taken. Particle counts for samples [redacted] and [redacted] were out of specification according to Federal Standard 209D, which you use as a reference.

   Additionally, validation for your ETO sterilization process is inadequate in that there is no written protocol or documentation of a heat distribution study, and you failed to identify a product lot for the validation.

2. Failure to establish and maintain procedures to control the design of the device in order to ensure that design requirements are met, as required by 21 CFR 820.30. For example, procedures to control the design of the device have not been established. Specifically, there are no written procedures for design input, output, review, verification, validation, change, and transfer.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, which may include detaining your devices without physical examination upon entry into the United States until corrections are completed. Section 801(a) of the Act, 21 U.S.C. 381(a).

In addition, Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

In addition, please be advised that we reviewed your labeling and noted you include a "FDA" logo in your promotional brochure. FDA clearance of your device does not constitute approval of your device, therefore, you cannot use any reference to FDA in your labeling or promotional literature. Any representation that creates an impression of official FDA approval of a device is misleading.

As of this date FDA has not received any response from your firm concerning our investigator's observations noted on the Inspectional Observations, FDA 483, issued at the closeout of the inspection.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion and documentation showing plans for correction should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review.

Please address your response to Paul Tilton, Chief, OB/Gyn, Gastroenterology, and Urology Devices Branch, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement A, 2098 Gaither Road, Rockville, Maryland 20850 USA.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Sharon Murrain-Ellerbe at the above address or at (301)594-4611 or FAX 301-594-4609.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health